UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ROTEM COHEN AND JASON BREUNING, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED, Plaintiffs, vs. KITOV PHARMACEUTICALS HOLDINGS LTD., ISAAC ISRAEL, and SIMCHA ROCK, Defendants.	**Civil Action No.: 17-cv-00917-LGS** **CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED**

Plaintiffs Rotem Cohen and Jason Breuning ("Plaintiffs"), individually and on behalf of all other persons similarly situated, by Plaintiffs' undersigned attorneys, for Plaintiffs' complaint against Defendants (defined below), allege the following based upon personal knowledge as to Plaintiffs their own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through their attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Kitov Pharmaceuticals Holdings Ltd. ("Kitov" or the "Company"), and information readily obtainable on the Internet. Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a class action on behalf of persons or entities who purchased or otherwise acquired Kitov's American Depository Shares ("ADSs") between November 20, 2015 and February 6, 2017, inclusive (the "Class Period"). Plaintiffs seek to recover compensable damages caused by Defendants' violations of the federal securities laws under the Securities Exchange Act of 1934 (the "Exchange Act").

2. The centerpiece of Kitov's business and the main attraction for investors was the commercialization of KIT-302, a development stage drug for the treatment of hypertension. At the time of its IPO, Kitov had just completed a final Phase 3 trial of KIT-302 and was in the process of preparing a new drug application ("NDA") to seek FDA approval to allow Kitov to begin selling KIT-302 and earning revenue.

3. Under Kitov's Special Protocol Agreement ("SPA") with the FDA, Kitov was obligated to submit its Phase 3 trial results to an independent Data Monitoring Committee ("DMC"). The DMC was to analyze the results and determine whether Kitov must recruit additional patients in order to demonstrate statistical validity and to meet the primary end point of the trial, and if so, the number of additional patients that would be required for a successful trial.

4. Ultimately, the true results of the KIT-302 trial did not achieve statistical significance and were not statistically valid. In other words, had they been submitted to the DMC, Kitov would have been forced to recruit additional patients at considerable cots.

5. Seeking to avoid the high costs of patient recruitment, Kitov's CEO Isaac Israel caused Kitov to provide falsified Phase 3 clinical trial results for KIT-302 to the DMC feigning statistical significance.

6. Providing the DMC with falsified data also allowed Kitov to meet its milestone deadline for successful completion of the clinical trial and allow JPW PCH LLC, which is majority owned by Kitov's Chairman, John Paul Waymack, to exercise its option to purchase 1,103,248 additional shares of Kitov stock under a shareholder rights agreement at a preferential price. Sincha Rock, the company's CFO, would also receive an option to purchase 181,089 upon achievement of the Milestone. Defendants' ability to claim that they met the primary endpoint in the KIT-302 trial also greatly facilitated Defendants' US IPO, completed less than one month later, and a subsequent secondary offering. Defendants' fraud was eventually revealed when Defendant Israel was arrested by the Israeli Securities Authority, charging him with fraud in connection with making false statements regarding the information provided to the Data Monitoring Committee.

JURISDICTION AND VENUE

7. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)).

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, and Section 27 of the Exchange Act (15 U.S.C. §78aa).

9. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). A significant portion of Defendants' actions and the subsequent damages, took place in this Judicial District.

10. In connection with the acts, conduct and other wrongs alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mails, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

11. Plaintiffs, as set forth in the certifications previously provided to the Court, purchased Kitov ADSs during the Class Period and were economically damaged thereby.

12. Defendant Kitov, through its subsidiary, is a clinical stage biopharmaceutical company that develops combination drugs for the simultaneous treatment of pain caused by osteoarthritis and hypertension. The Company's lead drug candidate is KIT-302. The Company is incorporated in Israel and its principal executive offices in Tel Aviv, Israel. Kitov's common stock is traded on the NASDAQ Capital Market ("NASDAQ") under the ticker symbol "KTOV."

13. Defendant Isaac Israel ("Israel") has been Kitov's Chief Executive Officer ("CEO") throughout the Class Period. Defendant Israel signed the Registration Statement.

14. Defendant Simcha Rock ("Rock") has been Kitov's Chief Financial Officer ("CFO") throughout the Class Period. Defendant Rock signed the Registration Statement.

15. Defendants Israel and Rock are collectively referred to herein as the "Individual Defendants."

16. Each of the Individual Defendants:

(a) directly participated in the management of the Company;

(b) was directly involved in the day-to-day operations of the Company at the highest levels;

(c) was privy to confidential proprietary information concerning the Company and its business and operations;

(d) was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;

(e) was directly or indirectly involved in the oversight or implementation of the Company's internal controls;

(f) was aware of or recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and/or

(g) approved or ratified these statements in violation of the federal securities laws.

17. Kitov is liable for the acts of the Individual Defendants and its employees under the doctrine of *respondeat superior* and common law principles of agency because all of the wrongful acts complained of herein were carried out within the scope of their employment.

18. The scienter of the Individual Defendants and other employees and agents of the Company is similarly imputed to Kitov under *respondeat superior* and agency principles.

19. Defendants Kitov and the Individual Defendants are collectively referred to herein as "Defendants."

Background Facts

20. Kitov was formed when Kitov Pharmaceuticals, Ltd. was acquired by Mainrom Line Logistics, Ltd., which subsequently changed its name to Kitov Pharmaceuticals Holdings, Ltd. Kitov's board chairman, Waymack, was the majority owner of Kitov Pharmaceuticals, LLC, via his limited liability company JPW PCH LLC. Pursuant to a shareholder rights agreement between Kitov Pharmaceuticals, Ltd and Mainrom, (the "2013 Shareholder Rights Agreement").

Under the terms of that agreement, the shareholders of Kitov Pharmaceuticals, Ltd would receive an additional 17,927,776 shares of Kitov stock upon completion of what the 2013 Shareholder Rights Agreement refers to as "the Milestone" by November 11, 2015. As set forth in the 2013 Shareholder Rights Agreement, "[t]he milestone will be met when the pivotal clinical trial has been completed, the data have been analyzed, and the data analyses have demonstrated that the reduction in blood pressure in the group treated with the Kitov drug KIT-302 was at least half of that achieved with amlodipine monotherapy." This milestone is the same as the KIT-302 trial's primary endpoint.

21. KIT-302 is Kitov's lead drug candidate and is a fixed dosage combination product based on the generic drugs celecoxib and amlodipine besylate, a drug designed to treat hypertension.

22. Prior to its IPO, Kitov agreed to a Special Protocol Assessment ("SPA") with the FDA. The SPA is a binding agreement that governed the design, subject inclusion criteria, minimum number of subjects, clinical endpoints, and specific statistical analyses for Kitov's Phase 3 study of KIT-302. In other words, once Kitov reached an agreement with the FDA on the SPA, Kitov was formally bound to conduct the Phase 3 trial and analyze the data collected from it in accordance with the terms established by the SPA.

23. A successful Phase 3 study conducted in strict accordance with the terms of the SPA forms the primary basis for any claim by Kitov that KIT-302 has shown "efficacy" that will be part of any New Drug Application ("NDA").

24. Failure to conduct the study or the planned analysis in accordance with the terms of the SPA will cause the FDA to reject the NDA. Falsifying clinical trial data would constitute

a breach of the SPA and would certainly result in the FDA rejecting the NDA, and may also constitute a federal crime.

25. In September of 2015 the board of directors of Kitov appointed an independent Data Monitoring Committee ("DMC") to evaluate whether Kitov's KIT-302 Phase 3 trial met its primary endpoint. The board also tasked DMC with reviewing the then-pending KIT-302 clinical trial and determining if and how many additional patients needed to be added to the trial to achieve a statistically valid result to meet FDA requirements for approval.

26. According to Defendants' 6-K dated December 1, 2015, Defendants provided information to the DMC on November 17, 2015. According to Defendants, on December 15, 2015 the DMC made a determination that the KIT-302 trial met its primary endpoint for efficacy and no additional patients would need to be enrolled.

27. In reality, the actual results of the KIT-302 trial failed to provide statistically significant evidence of efficacy. Therefore, as corroborated by several former employees of Kitov, Defendant Israel directed that the results of the KIT-302 trial be falsified prior to transmission to the DMC to improve the blood pressure data of patients who received treatment. This false data resulted in the DMC incorrectly finding that the KIT-302 trial met its primary endpoint. In so doing, Defendants avoided the costly endeavor of adding additional patients to the trial and caused Kitov to achieve the Milestone.

Materially False and Misleading Statements Issued During the Class Period

28. The Initial Registration Statement filed on form F-1/A on November 20, 2015 made several misstatements as set forth in the paragraphs below:

29. The Initial Registration Statement stated, on page 1:

> Our current pipeline consists of two clinical development therapeutic candidates, KIT-301 and KIT-302, which have been cleared for Phase III clinical trials, which will then be subject to review and approval by the FDA. Upon and subject to receipt of the requisite approvals, we intend to commercialize our therapeutic candidates through licensing and other commercialization arrangements with pharmaceutical companies on a global and/or territorial basis. We may also evaluate, on a case by case basis, co-development and similar arrangements, as well as independent commercialization of our therapeutic candidates.

30. The foregoing statement was misleading for stating that there was a prospect of approval from the FDA, when in reality Kitov had falsified KIT-302's clinical trial results and this doomed any prospect of FDA approval.

31. The Initial Registration Statement stated, on page 22:

> "You will experience further dilution if [by] November 11, 2015, we attain the milestone set forth in our 2013 Share Transfer Agreement pursuant to which we will issue 1,379,060 of our ordinary shares to the former shareholders of Kitov Pharmaceuticals. The independent external data monitoring committee responsible for analyzing the data required to determine whether the milestone set forth in the 2013 Share Transfer Agreement was met is expected to publish its intermediate findings by December 15, 2015. Until such time, we will not be able to determine whether the milestone triggering the issuance of 1,379,060 of our ordinary shares was met. See "Business - Share Transfer Agreement with Kitov Pharmaceuticals."

32. The foregoing statement was misleading for stating that the data had not yet been provided to the DMC, when in reality Kitov had already provided misleading clinical trial data to the DMC and these results were falsified by Kitov management under the direction of Isaac Israel to demonstrate statistical validity and to show the trial succeeded in meeting its primary endpoint for efficacy, guaranteeing the dilution of shares despite the failure of the KIT-302 clinical trial to genuinely achieve the milestone.

33. The Initial Registration Statement stated, on page 48:

> On November 7, 2013, we filed with the FDA the final statistical plan for the Phase III clinical trial protocol for KIT-302 as part of the FDA's Special Protocol Assessment, or SPA, procedures. On February 20, 2014, the FDA replied and

> indicated that the proposed data analysis of the trial's results that we submitted to the FDA provides a suitable solution to achieve the primary endpoint of the Phase III clinical trial and to support the final request for approval, which will be submitted…. The clinical trial is being performed using the Adaptive Trial Design method, or ATD, in accordance with the SPA. Based on the ATD format, in the first stage of the trial 150 patients are to be recruited. Then, the results of the trial will be disclosed to an independent external data monitoring committee, or DMC, which will analyze the results and determine the number of additional patients that we must recruit in order to demonstrate statistical validity and to meet the primary end point of the trial. To the extent the DMC recommends testing 200 or fewer additional patients, we will continue to recruit additional patients until reaching statistical validity and the primary end point of the trial. In the event that the DMC recommends testing more than 200 additional patients, our board will discuss the steps needed to complete such additional testing. If the trial generates the anticipated results, it would support our submission of a new drug application to FDA for KIT-302.

34. The foregoing statement was misleading for stating that data had not yet been provided to the DMC, when in reality Kitov had already provided the DMC with clinical trial results and these results were falsified by Kitov management under the direction of Isaac Israel, in an effort to demonstrate statistical validity and having met the primary endpoint of the trial, and avoid having to enroll additional patients which would be very costly and require Kitov to raise additional financing beyond their initial fundraising goals. Therefore, Defendants' claim that the trial had a chance of achieving the anticipated results that would support FDA approval was false when made – the results had been falsified precisely because Defendants knew the results otherwise would not support a successful NDA submission and FDA approval.

35. The Initial Registration Statement also stated, on page 49, that:

> For the development of KIT-302, we are performing a double blind, placebo controlled, Phase III clinical trial for testing the decrease of hypertension in patients receiving our KIT-302 drug product.
> …
>
> The Phase III clinical trial for KIT-302 is being conducted in medical centers in the United Kingdom on the basis of approvals received from the British Regulatory Authority (MHRA) and the U.K. ethics committees. It is not currently

> known whether the European regulatory authorities will require additional studies in order to grant their approval to market KIT-302 in Europe.
>
> If the results of the Phase III clinical trial present clear proof of the effectiveness of KIT-302, we will consider employing a similar development strategy for our second therapeutic candidate, KIT-301.

36. The foregoing statement was misleading because the KIT 302 trial already produced results that did not show clear proof of the effectiveness of KIT 302 and Defendants falsified the data provided to the DMC in an effort to falsely demonstrate clinical trial success and to avoid recruiting new patients for the trial.

37. The Initial Registration Statement also stated, on page 54:

> Special Protocol Assessment
>
> The special protocol assessment, or SPA, process is designed to facilitate the FDA's review and approval of drugs by allowing the FDA to evaluate the proposed design and size of Phase III clinical trials that are intended to form the primary basis for determining a drug product's efficacy. Upon specific request by a clinical trial sponsor, the FDA will evaluate the protocol and respond to a sponsor's questions regarding, among other things, primary efficacy endpoints, trial design and data analysis plans, within 45 days of receipt of the request.
>
> …
>
> Even if the FDA agrees to the design, execution and analyses proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement, such as under the following circumstances:
>
> - public health concerns emerge that were unrecognized at the time of the protocol assessment, or the director of the review division determines that a substantial scientific issue essential to determining safety or efficacy has been identified after testing has begun;
> - a sponsor fails to follow a protocol that was agreed upon with the FDA; or
> - the relevant data, assumptions or information provided by the sponsor in a request for SPA change, are found to be false statements or misstatements, or are found to omit relevant facts.

38. The foregoing was misleading for failing to disclose that Kitov had already provided falsified clinical trial data to the DMC and therefore its SPA was then currently subject to revocation by the FDA, which created a near certainty that the FDA would not approve the KIT-302 NDA.

39. The Initial Registration Statement stated, on page 60:

> On July 11, 2013, pursuant to a Share Transfer Agreement dated April 2, 2013 between Kitov Holdings, Kitov Pharmaceuticals, Dr. Morris Laster and JPW PCH LLC (Kitov Pharmaceutical's shareholders at the time), and the controlling shareholder in Kitov Holdings at such time, Mr. Sheer Roichman and Haiku Capital Ltd. (a private company wholly owned by Mr. Roichman), Kitov Holdings (then called Mainrom Line Logistics Ltd.) acquired the shares of Kitov Pharmaceuticals in exchange for the issuance of 1,351,478 ordinary shares to Kitov Pharmaceutical's shareholders, representing at the time 63.75% of the fully diluted share capital of Kitov Holdings. In addition, pursuant to the agreement, Kitov Holdings issued to the former shareholders of Kitov Pharmaceutical a right to purchase an additional 1,379,060 ordinary shares of Kitov Holdings if within 28 months from the completion of the acquisition, or November 11, 2015, we complete our Phase III clinical trial and the data analyses have demonstrated that the reduction in blood pressure in the group treated with KIT-302 was at least half of that achieved with amlodipine monotherapy, known as the Milestone. The independent external data monitoring committee responsible for the data analyses required to determine whether the Milestone was met, is expected to publish its intermediate findings by December 15, 2015. Until such time, we will not be able to determine whether the Milestone was met.

40. The foregoing statement was misleading for stating that Defendants would not be able to determine whether the Milestone was met until the DMC issued its findings with regard the Phase 3 clinical trial data. At the time the statement was made, Defendants had already provided falsified clinical trial data to the DMC under the direction of Isaac Israel to ensure a finding that the Milestone had been met, and thus guaranteeing the dilution of shares despite the failure of the clinical trial to yield the results necessary to genuinely achieve the milestone.

41. On December 1, 2015, in a press release on a Form 6-k, Ex 99.2, Defendants stated that

> On November 17, 2015 the Company announced that on November 16, 2015 test data was provided for 152 subjects of the Company's Phase II clinical trials, along with an initial statistical analysis, to the DMC committee, which will examine the data. The Company does not have and will not have access to this data until the test is completed by the Committee. The interim results are expected to be published by the Company by December 15, 2015.

42. The foregoing statement was misleading for failing to disclose that the Company had already reviewed the data prior to providing it to the DMC, determined that it would result in the DMC failing to find statistically significant evidence of efficacy without more patients added to the trial, and that therefore Defendants altered that data before providing it to the DMC.

43. On December 15, 2015, in a press release on a Form 6-k 99.1, Defendants stated that:

> Tel Aviv, Israel, December 15, 2015 – Kitov Pharmaceuticals (NASDAQ/TASE: KTOV), an innovative biopharmaceutical company focused on late-stage drug development, announced today that the Phase III, double-blind, placebo-controlled clinical trial for its leading drug candidate, KIT-302, successfully met the primary efficacy endpoint of the trial protocol as approved by the U.S. Food & Drug Administration (FDA). Data from the trial further revealed that KIT-302 was more efficacious at reducing hypertension than the widely used hypertension drug amlodipine besylate. Kitov plans to file its New Drug Application (NDA) for marketing approval of KIT-302 with the FDA in the second half of 2016….
>
> The trial results demonstrated that the number of 152 patients treated was found to be adequate to provide statistical validity and therefore, the results are final. These final results show that in patients treated with amlodipine besylate only, there was a mean reduction in daytime systolic blood pressure of 8.8 mm Hg. In patients treated with KIT-302, there was a mean reduction in daytime systolic blood pressure of 10.6 mm Hg. Therefore, the primary efficacy endpoint of the study has been successfully achieved with a p value of 0.001.

44. The foregoing statement was misleading for falsely stating that the Phase 3 trial had met the primary efficacy endpoint and provided "statistical validity," and for failing to disclose that the KIT-302 trial failed to show statistically significant evidence of efficacy and

that as a result Defendants altered the blood pressure results for the KIT 302 trial before providing the data to the DMC.

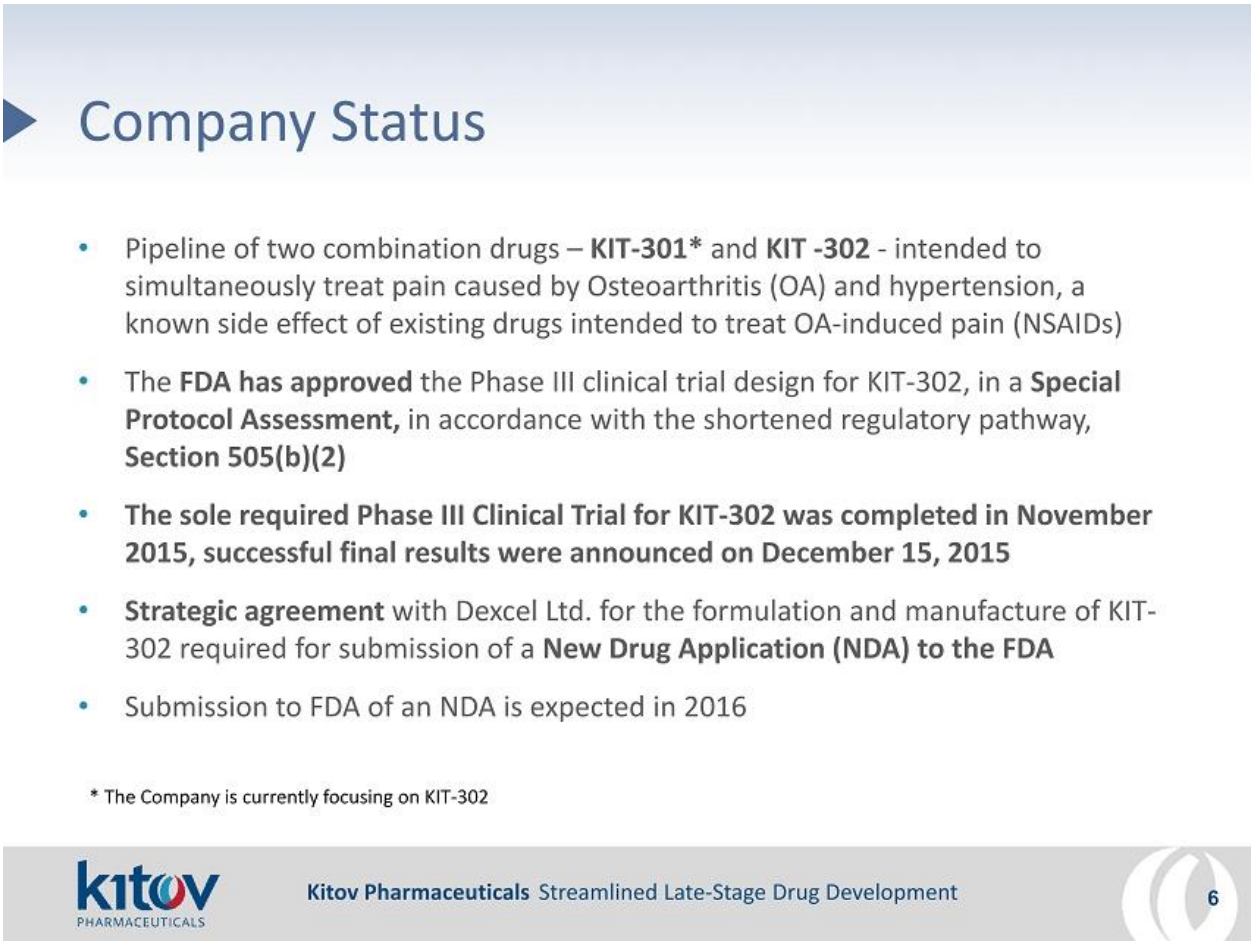
45. In a press release on Form 6k, dated December 15, 2015, Defendants stated that

> The Company is announcing that with the completion of the statistical analysis, the Phase III clinical trial for its leading drug candidate, KIT-302, successfully met the primary efficacy endpoint of the trial protocol. As the trial results demonstrated that, the primary efficacy endpoint of the study has been successfully achieved, there is no need to recruit additional patients, and therefore, the results are final.
>
> …
>
> Furthermore, the final results show that not only was the primary efficacy end-point of the trial achieved, but that in patients from group (a) treated with KIT-302, there was a mean reduction in daytime systolic blood pressure of 10.6 mm Hg, which was more than the mean reduction in daytime systolic blood pressure of 8.8 mm Hg seen in patients from group (c) who were treated with blood pressure reduction medication only (p value of 0.001).
>
> The Company intends to continue with the planned chemical development of the product, to conduct a final PK trial during the first half of 2016, and to submit a New Drug Application to the FDA during the second half of 2016.
> …
>
> "We are very pleased with the successful and final outcome of our pivotal Phase III trial and we look forward to meeting with the FDA in the near future to finalize plans for our NDA submission. We believe we will be ready to submit the NDA for KIT-302 in the second half of 2016. Should the NDA meet with the FDA's approval, we would expect to receive marketing approval in 2017," stated Kitov CEO Isaac Israel.
>
> "Data revealing that KIT-302 is more efficacious at reducing daytime systolic blood pressure than amlodipine besylate alone was particularly compelling. We are now conducting an in depth analysis of the robust data produced in this trial, and we look forward to sharing other findings that may be of interest to the medical community," commented Dr. J. Paul Waymack, Chairman of Kitov's Board and Chief Medical Officer.
>
> "KIT-302 has the potential to address the multi-billion dollar market for the treatment of osteoarthritis pain and hypertension with one drug that reduces patients' risk of suffering a heart attack or stroke, while also reducing cost for payers. There is currently no single medication on the market that treats both

osteoarthritis pain and hypertension and thus, KIT-302 will be the only NSAID indicated both to treat pain and to reduce the risk of heart attack, stroke and death."

46. The foregoing statement was misleading because Defendants falsified the blood pressure results for the KIT 302 trial before providing the data to the DMC.to mislead the DMC and FDA that the Phase 3 trial had reached statistical validity andmet the primary efficacy endpoint. In truth the clinical trial was not statistically valid and did not demonstrate efficacy or meet the primary endpoint in the trial.

47. In an investor presentation on Form 6-k ex 99.2 January 11, 2016, Defendants stated that:



48. The foregoing statement was misleading for failing to disclose that Defendants falsified the data for the KIT-302 trial and that the results of the KIT-302 trial were not in reality successful.

49. In an annual report on Form 20-F for the year 2015, dated March 16, 2016, Defendants stated on Page 38:

> On November 7, 2013, we filed with the FDA the final statistical plan for the Phase III clinical trial protocol for KIT-302 as part of the SPA procedures. On February 20, 2014, the FDA replied and indicated that the proposed data analysis of the trial's results that we submitted to the FDA provides a suitable solution to achieve the primary endpoint of the Phase III clinical trial and to support the final request for approval, which will be submitted. As a result of the SPA process, the FDA approved the Phase III trial design for our clinical trial, and cleared our clinical trial to begin, and on June 18, 2014, we commenced the clinical trial, as described below. The clinical trial was performed using the Adaptive Trial Design method, or ATD, in accordance with the SPA. Based on the ATD format, in the first stage of the trial 150 patients were to be recruited. Then, the results of the trial were to be disclosed to an independent external data monitoring committee, which was then to analyze the results and determine the number of additional patients that we might have needed to recruit in order to demonstrate statistical validity and to meet the primary end point of the trial.
>
> The interim analysis has been completed and documented such that no further patients needed to be enrolled. The final analysis of the data was then undertaken and it determined that KIT-302 had met its FDA approved primary efficacy endpoint.

50. The foregoing statement was misleading for falsely stating that the Phase 3 trial results had met the primary efficacy endpoint and provided "statistical validity". In truth, the KIT-302 trial failed to show statistically significant evidence of efficacy and the Defendants had falsified the blood pressure results for the KIT 302 trial before providing the data to the DMC.

51. In an annual report on 20-F for the year 2015, dated March 16, 2016, Defendants stated on page 14:

> We have reached an agreement with the FDA to conduct the Phase III clinical trial for KIT-302 pursuant to an SPA agreement…. [A]n SPA agreement is not

> binding on the FDA if public health concerns emerge that were unrecognized at the time of the SPA agreement, other new scientific concerns regarding product safety or efficacy arise, the sponsor company fails to comply with the agreed upon trial protocols, or the relevant data, assumptions or information provided by the sponsor in a request for the SPA change or are found to be false or omit relevant facts…. While we believe that our Phase III clinical trial has been completed in accordance with the SPA agreement, and that the data generated met the endpoints that have been agreed in the SPA agreement to represent adequate evidence of effectiveness, if the FDA revokes or alters its agreement under the SPA agreement, or if the FDA interprets the data collected from the clinical trial differently than we do, the FDA may not deem the data sufficient to support an application for regulatory approval, which could materially adversely affect our business, financial condition and results of operations.

52. The foregoing statement was misleading for failing to disclose that Defendants falsified clinical trial results with respect to patient blood pressure and that therefore, the statistical analysis plan was not conducted according to the SPA and the SPA was already subject to revocation, and for failing to disclose that Defendants were aware that the true results of the KIT-302 trial did not support FDA approval.

53. In an annual report on Form 20-F for the year 2015, dated March 16, 2016, Defendants stated on page 32:

> On December 15, 2015, we announced that the Phase III, double-blind, placebo-controlled clinical trial for our leading drug candidate, KIT-302, successfully met the primary efficacy endpoint of the trial protocol as approved by the FDA. Data from the trial further revealed that KIT-302 tended to reduce blood pressure more than the widely used hypertension drug amlodipine besylate when administered alone. We plan to file our NDA for marketing approval of KIT-302 with the FDA in the second half of 2016.
>
> …
>
> The trial results demonstrated that the number of 152 patients treated was found to be adequate to provide statistical validity and therefore, the results were final. These final results showed that in patients treated with amlodipine besylate only, there was a mean reduction in daytime systolic blood pressure of 8.8 mm Hg. In patients treated with KIT-302, there was a mean reduction in daytime systolic blood pressure of 10.6 mm Hg. Therefore, the primary efficacy endpoint of the study has been successfully achieved with a p value of 0.001.

54. The foregoing statements were misleading for falsely stating that the Phase 3 trial had met the primary efficacy endpoint and provided "statistical validity," and for failing to disclose that the true data of the KIT 302 trial failed to support a finding of efficacy and that Defendants had falsified blood pressure data before submitting the data to the DMC.

55. In an annual report on Form 20-F for the year 2015, dated March 16, 2016, defendants stated on page 39:

> We currently expect to receive approval from the FDA to market KIT-302 in 2017. As a result of this timing and because KIT-302 combines the treatment of osteoarthritis by celecoxib with amlodipine besylate, which treats the side effect of hypertension, we believe that KIT-302 may be an attractive alternative to the newly marketed generic versions of Celebrex®

56. The foregoing statement was misleading because Defendants had falsified clinical trial results with respect to patient blood pressure in order to fake statistical validity and misrepresent that the trial met its primary endpoint for efficacy. As a result, the SPA was subject to revocation, and Defendants were aware that the true results of the KIT-302 trial did not support FDA approval.

57. In an annual report on Form 20-F for the year 2015, dated March 16, 2016, defendants stated on pages 39-40:

> For the development of KIT-302, we performed a double blind, placebo controlled, Phase III clinical trial for testing the decrease of hypertension in patients receiving our KIT-302 therapeutic candidate.
>
> …
>
> We announced the top line trial results in December 2015, showing that we successfully met the primary efficacy endpoint of the trial protocol as approved by the FDA. Data from the trial further revealed that KIT-302 tended to reduce blood pressure more than the widely used hypertension drug amlodipine besylate alone.

> The trial results demonstrated that the number of 152 patients treated was adequate to provide statistical validity and therefore, the results were final. These final results showed that in patients treated with amlodipine besylate only, there was a mean reduction in daytime systolic blood pressure of 8.8 mm Hg. In patients treated with KIT-302, there was a mean reduction in daytime systolic blood pressure of 10.6 mm Hg. Therefore, the primary efficacy endpoint of the study has been successfully achieved with a p value of 0.001.

58. The foregoing statement was false for stating that the Phase 3 trial had met the primary efficacy endpoint and provided "statistical validity," as Defendants has falsified the clinical trial results with respect to patient blood pressure in order to feign statistical significance. Thus, Defendants were aware that the true results of the KIT-302 trial did not support FDA approval.

59. On March 18, 2016, Defendants filed a Post-effective Amendment to their registration statement that stated, on page 3:

> Announcement of Clinical Trial Results
>
> On December 15, 2015, we announced that the Phase III, double-blind, placebo-controlled clinical trial for our leading drug candidate, KIT-302, successfully met the primary efficacy endpoint of the trial protocol as approved by the FDA. Data from the trial further revealed that KIT-302 tended to reduce blood pressure more than the widely used hypertension drug amlodipine besylate when administered alone. We plan to file our NDA for marketing approval of KIT-302 with the FDA in the second half of 2016.
>
> The trial protocol, approved by the FDA through the SPA process, was designed to quantify the decrease of hypertension in patients receiving KIT-302. The trial was performed in the U.K. in four groups of twenty-six (26) to forty-nine (49) patients, with a total of 152 patients. Each patient was treated over a total period of two weeks. Group One was treated with KIT-302, comprised of celecoxib and amlodipine besylate. Group Two was treated with amlodipine besylate only, one of the components of KIT-302. Group Three was treated with celecoxib only, the other component of KIT-302. Group Four was treated with a double placebo. The trial began in June 2014 and was completed in November 2015.
>
> The trial results demonstrated that the number of 152 patients treated was found to be adequate to provide statistical validity and therefore, the results were final.

> These final results showed that in patients treated with amlodipine besylate only, there was a mean reduction in daytime systolic blood pressure of 8.8 mm Hg. In patients treated with KIT-302, there was a mean reduction in daytime systolic blood pressure of 10.6 mm Hg. Therefore, the primary efficacy endpoint of the study has been successfully achieved with a p value of 0.001.

60. The foregoing statements that (i) the Phase 3 trial had successfully met the primary efficacy endpoint of the trial protocol as approved by the FDA; and (ii) the trial results demonstrated that the number of 152 patients treated was found to be adequate to provide statistical validity and therefore, the results were final were false and misleading because Defendants had falsified the clinical trial results to falsely show statistical validity and efficacy.. .

61. In an annual report on Form 20-F for the year 2015, dated March 16, 2016, Defendants stated on page 37:

> We believe that our current cash and cash equivalents are sufficient to complete the research and development of KIT-302 until its anticipated approval for marketing by the FDA in 2017.

62. The foregoing statement was misleading because Defendants had falsified the clinical trial data, and KIT-302 had no chance for approval in 2017 or at any time based on the clinical trials to date, and therefore, additional cash would be required to complete the research and development of KIT-302 until its approval.

63. In an annual report on Form 20-F for the year 2015, dated March 16, 2016, Defendants stated on page 38:

> Due to the inherently unpredictable nature of clinical development processes, we are unable to estimate with any certainty the costs we will incur in the continued development of our therapeutic candidates for potential commercialization. We estimate a total cost of approximately $500,000 of research and development expenses related to the Phase III clinical trial for KIT-302, $750,000 in order to complete the CMC work for KIT-302, and $500,000 for the final formulation PK trial for KIT-302. In addition, we will incur cost of approximately $150,000 to prepare for the Phase III clinical trial for KIT-301.

64. The foregoing statement was misleading for failing to disclose that the true KIT-302 data did not show statistically significant or valid results and that therefore substantial additional funding would be required to finance further clinical testing before KIT-302 could be approved by FDA.

65. In an annual report on Form 20-F for the year 2015, dated March 16, 2016, Defendants stated on page 46:

> On November 7, 2013, we filed with the FDA the final statistical plan for the Phase III clinical trial protocol for KIT-302 as part of the SPA procedures. On February 20, 2014, the FDA replied and indicated that the proposed data analysis of the trial's results that we submitted to the FDA provides a suitable solution to achieve the primary endpoint of the Phase III clinical trial and to support the final request for approval, which will be submitted. As a result of the SPA process, the FDA approved the Phase III trial design for our clinical trial, and cleared our clinical trial to begin, and on June 18, 2014, we commenced the clinical trial, as described below. The clinical trial was performed using the Adaptive Trial Design method, or ATD, in accordance with the SPA. Based on the ATD format, in the first stage of the trial 150 patients were to be recruited. Then, the results of the trial were to be disclosed to an independent external data monitoring committee, which was then to analyze the results and determine the number of additional patients that we might have needed to recruit in order to demonstrate statistical validity and to meet the primary end point of the trial.
>
> The interim analysis has been completed and documented such that no further patients needed to be enrolled. The final analysis of the data was then undertaken and it determined that KIT-302 had met its FDA approved primary efficacy endpoint.

66. The foregoing statement was misleading for falsely stating that the Phase 3 trial demonstrated that no further patients need be enrolled and that the KIT-302 clinical trial had met the primary efficacy endpoint." In truth, Defendants falsified the results of the KIT-302 Phase 3 trial. Had the true results been presented to the FDA or DMC, Kitov would have had to recruit and test additional patients, as neither statistical validity, nor efficacy, had been shown in the trial.

67. In an annual report on Form 20-F for the year 2015, dated March 16, 2016, Defendants stated on page 47:

> For the development of KIT-302, we performed a double blind, placebo controlled, Phase III clinical trial for testing the decrease of hypertension in patients receiving our KIT-302 therapeutic candidate. This trial was performed in the U.K. in four groups of twenty-six (26) to forty-nine (49) patients (a total of 152 patients), with each patient treated over a total period of two weeks. …
>
> We announced the top line trial results in December 2015, showing that we successfully met the primary efficacy endpoint of the trial protocol as approved by the FDA. Data from the trial further revealed that KIT-302 tended to reduce blood pressure more than the widely used hypertension drug amlodipine besylate alone.
>
> The trial results demonstrated that the number of 152 patients treated was adequate to provide statistical validity and therefore, the results were final. These final results showed that in patients treated with amlodipine besylate only, there was a mean reduction in daytime systolic blood pressure of 8.8 mm Hg. In patients treated with KIT-302, there was a mean reduction in daytime systolic blood pressure of 10.6 mm Hg. Therefore, the primary efficacy endpoint of the study has been successfully achieved with a p value of 0.001.

68. The foregoing statement was misleading for falsely stating that the Phase 3 trial had met the primary efficacy endpoint and provided "statistical validity." In truth, Defendants falsified the blood pressure data of patients in the KIT-302 trial in order to show statistical validity and achieve their primary efficacy endpoint. Had they not done so, the true data would have failed to produce statistically valid and significant evidence of efficacy.

69. In a post-effective prospectus amendment on form 424b3 dated May 16, 2016, defendants stated that

> On December 15, 2015, we announced that the Phase III, double-blind, placebo-controlled clinical trial for our leading drug candidate, KIT-302, successfully met the primary efficacy endpoint of the trial protocol as approved by the FDA. Data from the trial further revealed that KIT-302 tended to reduce blood pressure more than the widely used hypertension drug amlodipine besylate when administered alone. We plan to submit our NDA for marketing approval of KIT-302 with the FDA at the end of 2016.

…

> The trial results showed that in patients treated with amlodipine besylate only, there was a mean reduction in daytime systolic blood pressure of 8.8 mm Hg. In patients treated with KIT-302, there was a mean reduction in daytime systolic blood pressure of 10.6 mm Hg. Therefore, the primary efficacy endpoint of the study has been successfully achieved with a p value of 0.001.

70. The foregoing statement was falsely stated that the Phase 3 trial had met the primary efficacy endpoint. In truth, Defendants falsified the data before providing it to the DMC and FDA. The KIT 302 trial did not produce results that provided statistically significant evidence of efficacy.

71. In a proxy statement dated May 24, 2016, Defendants stated that:

> In addition to the above review of market trends and benchmarking, in proposing the below changes to Mr. Israel's terms of office and employment, the Audit Committee and the Board recognized the growth of the Company achieved under his leadership since 2013. Most significantly, under Mr. Israel's leadership, the Company achieved a successful clinical trial for its flagship product KIT-302, and also received an allowance to grant a patent from the USPTO for its products.
>
> Following the attainment of the Milestone under the Share Transfer Agreement in connection with our Phase III trial for KIT-302 (as described in our Annual Report for 2015 on Form 20-f), we were required to grant to Mr. Rock an additional 181,089 options to purchase 13,929 ordinary shares.
>
> Most significantly, under Dr. Waymack's leadership, the Company achieved a successful clinical trial for its flagship product KIT-302, and also received an allowance to grant a patent from the USPTO for its products.

72. The foregoing statement was misleading for falsely stating that the Company had achieved a successful clinical trial for KIT-302. In truth, Defendants falsified the KIT-302 clinical trial data before providing it to the DMC and FDA to mislead investors, the DMC and the FDA to believe the clinical trial was successful.

73. In a press release filed on Form 6k ex 99.1 dated June 24, 2016, Defendants stated in relevant part:

> The Phase III, double-blind, placebo-controlled trial protocol, approved by the FDA through the Special Protocol Assessment (SPA) process, was designed to quantify the decrease of hypertension in patients receiving KIT-302. The trial was performed in the U.K. in four groups of 26 to 49 patients each, with a total of 152 patients in the trial. Each patient was treated over a total period of two weeks. Group One was treated with KIT-302, a combination of celecoxib and amlodipine besylate. Group Two was treated with amlodipine besylate only, one of the components of KIT-302. Group Three was treated with celecoxib only, the other component of KIT-302. Group Four was treated with a double placebo.
>
> The primary efficacy end-point of the trial was to show that a combination of the two components of KIT-302, as demonstrated in Group One, lowers daytime systolic blood pressure by at least 50% of the reduction in blood pressure achieved in patients in Group Two, who were treated with amlodipine besylate only. The final results showed that in patients treated with amlodipine besylate only, there was a mean reduction in daytime systolic blood pressure of 8.8 mm Hg. In patients treated with KIT-302, there was a mean reduction in daytime systolic blood pressure of 10.6 mm Hg. Therefore, the primary efficacy endpoint of the study was successfully achieved with a p-value of 0.001.

74. The foregoing statement was misleading for falsely stating that the Phase 3 trial had met the primary efficacy endpoint. In truth, Defendants falsified the clinical trial data for the KIT-302 trial because the trial did not meet its primary endpoint for efficacy.

75. On June 27, 2016, Kitov filed an amended Secondary Registration Statement on form F-1/A in connection with its Secondary Offering.

76. The Secondary Registration Statement stated, on page 3:

> On December 15, 2015, we announced that the Phase III, double-blind, placebo-controlled clinical trial for our leading drug candidate, KIT-302, successfully met the primary efficacy endpoint of the trial protocol as approved by the FDA. Data from the trial further revealed that KIT-302 tended to reduce blood pressure more than the widely used hypertension drug amlodipine besylate when administered alone. We plan to submit our NDA for marketing approval of KIT-302 with the FDA at the end of 2016.
>
> The trial protocol, approved by the FDA through the SPA process, was designed to quantify the decrease of hypertension in patients receiving KIT-302. The trial was performed in the U.K. in four groups of twenty-six (26) to forty-nine (49) patients, with a total of 152 patients. Each patient was treated over a total period of two weeks. Group One was treated with KIT-302, comprised of celecoxib and

> amlodipine besylate. Group Two was treated with amlodipine besylate only, one of the components of KIT-302. Group Three was treated with celecoxib only, the other component of KIT-302. Group Four was treated with a double placebo. The trial began in June 2014 and was completed in November 2015.
>
> The primary efficacy end-point of the trial was to show that a combination of the two components of KIT-302, as demonstrated in Group One, lowers daytime systolic blood pressure by at least 50% of the reduction in blood pressure achieved in patients in Group Two, who were treated with amlodipine besylate only.
>
> The trial results showed that in patients treated with amlodipine besylate only, there was a mean reduction in daytime systolic blood pressure of 8.8 mm Hg. In patients treated with KIT-302, there was a mean reduction in daytime systolic blood pressure of 10.6 mm Hg. Therefore, the primary efficacy endpoint of the study has been successfully achieved with a p value of 0.001.

77. The foregoing statement was misleading for falsely stating that the Phase 3 trial had met the primary efficacy endpoint. In truth, Defendants falsified the clinical trial data for the KIT-302 trial because the trial did not meet its primary endpoint for efficacy. As a result any NDA would most certainly be rejected by the FDA.

78. The Secondary Registration Statement stated, on page 15:

> We have reached an agreement with the FDA to conduct the Phase III clinical trial for KIT-302 pursuant to an SPA agreement. The FDA's SPA process is designed to facilitate the FDA's review and approval of drugs by allowing the FDA to evaluate the proposed design and size of Phase III trials that are intended to form the primary basis for determining a therapeutic candidate's efficacy.…[A]n SPA agreement is not binding on the FDA if public health concerns emerge that were unrecognized at the time of the SPA agreement, other new scientific concerns regarding product safety or efficacy arise, the sponsor company fails to comply with the agreed upon trial protocols, or the relevant data, assumptions or information provided by the sponsor in a request for the SPA change or are found to be false or omit relevant facts.

79. The foregoing statement was misleading for failure to disclose Kitov had falsified KIT-302 data and therefore violated the SPA, subjecting it to revocation.

80. The Secondary Registration Statement stated, on page 35:

> We believe that our current cash and cash equivalents are sufficient to complete the research and development of KIT-302 until its anticipated approval for marketing by the FDA in 2017.

81. The foregoing statement was misleading because Defendants had falsified the clinical trial data, and KIT-302 had no chance for approval in 2017 or at any time based on the clinical trials to date, and therefore, additional cash would be required to complete the research and development of KIT-302 until its approval.

82. The Secondary Registration Statement stated, on page 44:

> On November 7, 2013, we filed with the FDA the final statistical plan for the Phase III clinical trial protocol for KIT-302 as part of the SPA procedures. On February 20, 2014, the FDA replied and indicated that the proposed data analysis of the trial's results that we submitted to the FDA provides a suitable solution to achieve the primary endpoint of the Phase III clinical trial and to support the final request for approval, which will be submitted. As a result of the SPA process, the FDA approved the Phase III trial design for our clinical trial, and cleared our clinical trial to begin, and on June 18, 2014, we commenced the clinical trial, as described below. The clinical trial was performed using the Adaptive Trial Design method, or ATD, in accordance with the SPA. Based on the ATD format, in the first stage of the trial 150 patients were to be recruited. Then, the results of the trial were to be disclosed to an independent external data monitoring committee, which was then to analyze the results and determine the number of additional patients that we might have needed to recruit in order to demonstrate statistical validity and to meet the primary end point of the trial.
>
> The interim analysis has been completed and documented such that no further patients needed to be enrolled. The final analysis of the data was then undertaken and it determined that KIT-302 had met its FDA approved primary efficacy endpoint.

83. The foregoing statement was misleading for falsely stating that (i) the Phase 3 trial had provided "statistical validity," (ii) no additional patients needed to be enrolled, and (iii) the Phase 3 trial met the primary efficacy endpoint. In truth, Defendants falsified the trial results provided to the DMC with respect to patient blood pressure in order to fake statistical validity and significance and to avoid recruiting/testing additional patients.

84. The Secondary Registration Statement stated, on page 45:

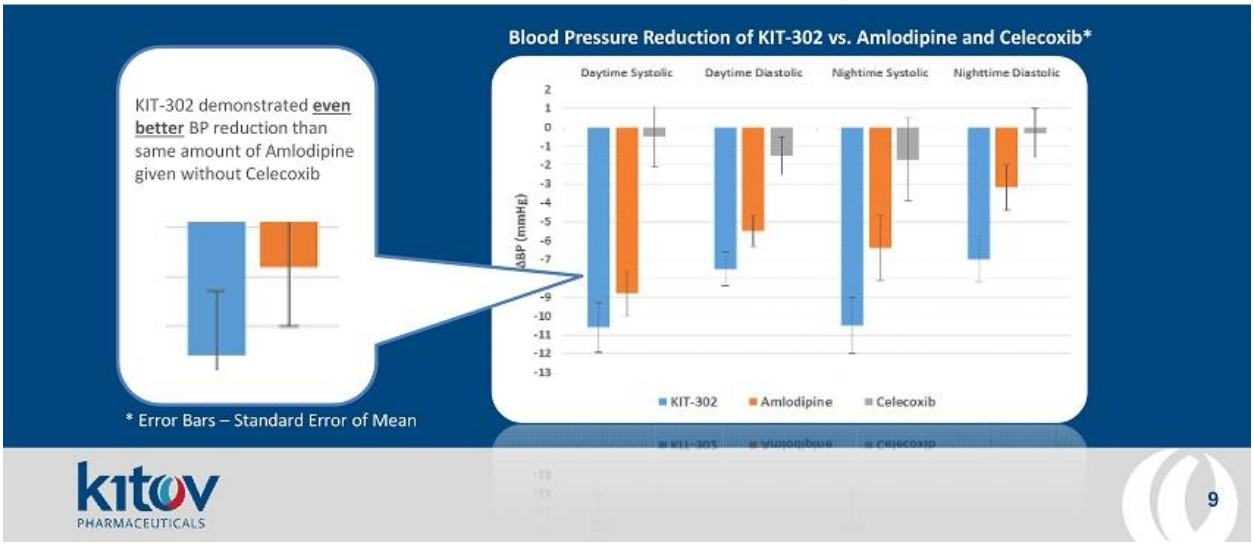
> The trial results showed that in patients treated with amlodipine besylate only, there was a mean reduction in daytime systolic blood pressure of 8.8 mm Hg. In patients treated with KIT-302, there was a mean reduction in daytime systolic blood pressure of 10.6 mm Hg. Therefore, the primary efficacy endpoint of the study has been successfully achieved with a p value of 0.001.
>
> Additional data from the trial results showed the favorable blood pressure effects of KIT-302 were present in all blood pressure variables measured in the study. The data indicated that the blood pressure reduction synergy seen with combining celecoxib and amlodipine, is seen not only in the study's primary efficacy endpoint of daytime systolic blood pressure, but was also seen for daytime diastolic blood pressure measurements, and in all other blood pressure variables.

85. The foregoing statement was misleading for falsely stating that the Phase 3 trial had met the primary efficacy endpoint. In truth, Defendants falsified KIT-302's blood pressure data to fake a successful trial.

In an investor presentation filed on Form 6-k, dated September 7, 2016, Defendants stated in relevant part:

KIT-302 Phase III Trial Results

- Results announced December 15, 2015
- Primary efficacy end-point was successfully achieved (P=0.001)
- Demonstrated 2.5x better blood pressure (BP) reduction than FDA requirement (50% of Amlodipine alone arm)
- Demonstrated consistent reduction in all measures of blood pressure



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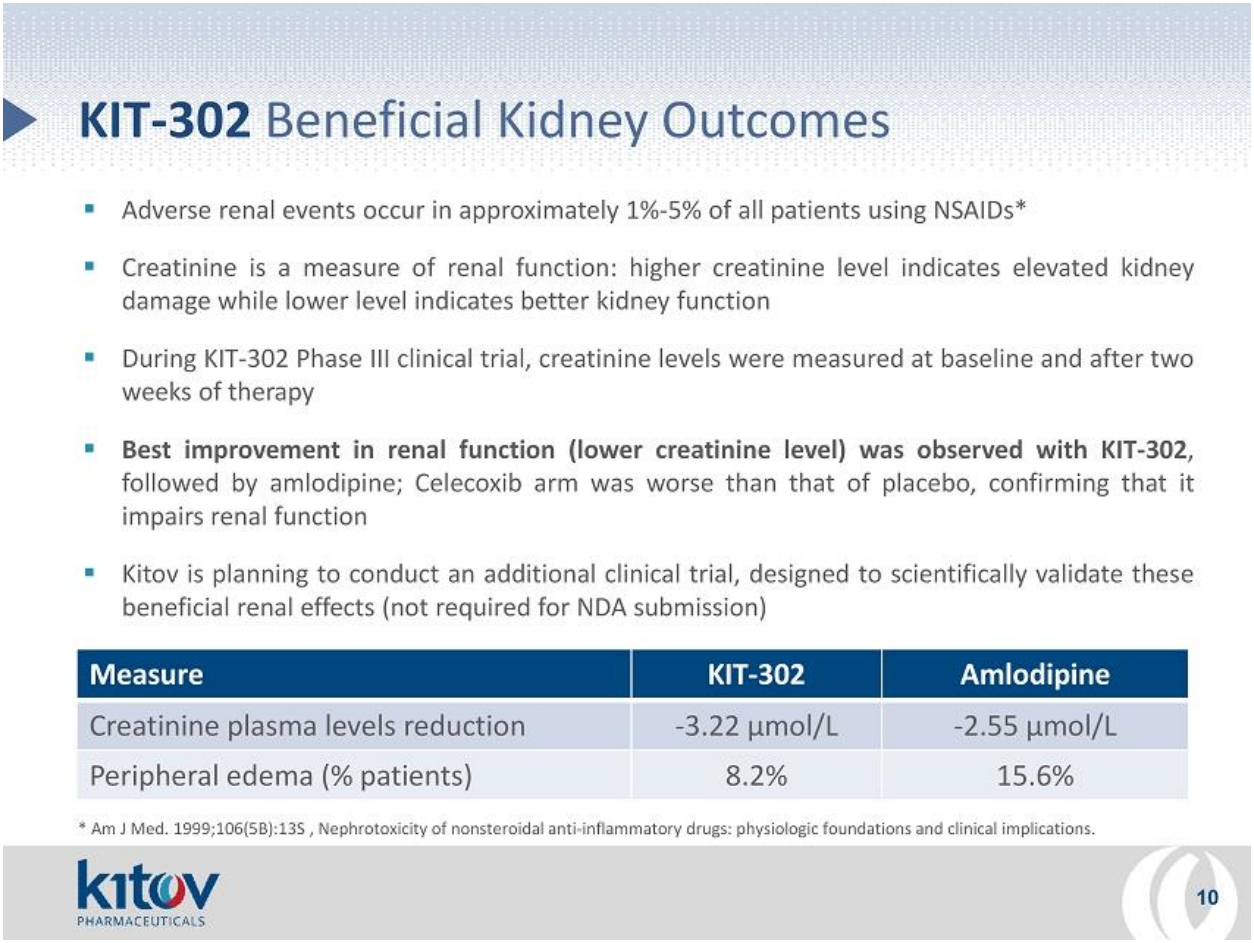

KIT-302 Beneficial Kidney Outcomes

- Adverse renal events occur in approximately 1%-5% of all patients using NSAIDs*
- Creatinine is a measure of renal function: higher creatinine level indicates elevated kidney damage while lower level indicates better kidney function
- During KIT-302 Phase III clinical trial, creatinine levels were measured at baseline and after two weeks of therapy
- **Best improvement in renal function (lower creatinine level) was observed with KIT-302**, followed by amlodipine; Celecoxib arm was worse than that of placebo, confirming that it impairs renal function
- Kitov is planning to conduct an additional clinical trial, designed to scientifically validate these beneficial renal effects (not required for NDA submission)

Measure	KIT-302	Amlodipine
Creatinine plasma levels reduction	-3.22 µmol/L	-2.55 µmol/L
Peripheral edema (% patients)	8.2%	15.6%

* Am J Med. 1999;106(5B):13S , Nephrotoxicity of nonsteroidal anti-inflammatory drugs: physiologic foundations and clinical implications.

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86. The foregoing statements were misleading for falsely stating that the Phase 3 trial had met the primary efficacy endpoint and, when in truth, Defendants falsified the Phase 3 blood pressure data to fake a successful outcome for the trial.

87. In a registration statement on Form f-3, dated November 28, 2016, Defendants stated on page 4:

> On December 15, 2015, we announced that the Phase III, double-blind, placebo-controlled clinical trial for our leading drug candidate, KIT-302, successfully met the primary efficacy endpoint of the trial protocol as approved by the FDA. Data from the trial further revealed that KIT-302 tended to reduce blood pressure more than the widely used hypertension drug amlodipine besylate when administered alone. We plan to submit our NDA for marketing approval of KIT-302 with the FDA in the coming months.

…

> The trial results showed that in patients treated with amlodipine besylate only, there was a mean reduction in daytime systolic blood pressure of 8.8 mm Hg. In patients treated with KIT-302, there was a mean reduction in daytime systolic blood pressure of 10.6 mm Hg. Therefore, the primary efficacy endpoint of the study has been successfully achieved with a p value of 0.001.

88. The foregoing statement was misleading for falsely stating that the Phase 3 trial had met the primary efficacy endpoint. In truth, Defendants falsified the clinical trial data for the KIT-302 trial because the trial did not meet its primary endpoint for efficacy. As a result, any NDA would most certainly be rejected by the FDA.

THE TRUTH EMERGES

89. On February 6, 2017, the Israeli publication *Calcalist* reported that Defendant Israel, Kitov's CEO, had been detained and questioned by the Israel Securities Authority on suspicion of publishing misleading information to investors in the US and Israel in connection with the clinical trial of KIT-302. The *Calcalist* article stated that the Israeli Securities Authority found that Kitov made misleading statements in immediate and periodic reports filed with securities authorities beginning in December 2015, as well as the July 2016 Prospectus filed with the SEC, regarding the conclusions reached by the DMC.[1] The article went on to state that, according to the Israeli Securities Authority, the misleading statements were made with the knowledge of Israel.

90. On this news, the price of Kitov's ADSs fell $0.33 per share, or 11.46%, to close at $2.55 per share on February 6, 2017, and the price of Kitov's warrants fell $0.10 per warrant, or 10%, to close at $0.89 per warrant on February 6, 2017.

[1] An immediate report under Israel's securities laws is equivalent to a Form 8-K report filed upon occurrence of a material event under U.S. securities laws.

91. On February 7, 2017, NASDAQ halted trading in Kitov's ADSs and warrants prior to market open.

92. On February 7, 2017, Kitov issued a press release announcing that the Israeli Securities Authority had begun a formal investigation into the Company's public disclosures concerning its lead drug candidate, KIT-302, stating in pertinent part:

> TEL AVIV, Israel, Feb. 07, 2017 (GLOBE NEWSWIRE) -- Kitov Pharmaceuticals Holdings Ltd. (NASDAQ:KTOV) (TASE:KTOV), an innovative biopharmaceutical company, announced today that the Israeli Securities Authority has begun a formal investigation into the Company's public disclosures around its lead drug candidate, KIT-302.
>
> J. Paul Waymack, M.D., Sc.D., Chairman of the Board and Chief Medical Officer, stated, "Kitov stands fully behind the validity of all of its clinical trial results. The Company continues to move forward toward the filing of our New Drug Application for KIT-302 with the FDA."

93. On February 9, 2017, NASDAQ announced that Kitov's ADSs and warrants would resume trading on February 9, 2017, at 10:45 Eastern Standard Time.

94. As soon as shares of Kitov's ADSs began trading again, their price immediately incorporated the negative news issued concerning the investigation and the price fell $0.36 per share, or 14%, to close at $2.19 on February 9, 2017, and the price of Kitov's warrants fell $0.27 per warrant, or 30%, to close at $0.62 per warrant on February 9, 2017.

95. On May 1, 2017 the Company stated that the Israeli Securities Agency's investigation related to the information actually provided to the DMC by the Company.

ADDITIONAL ALLEGATIONS SUPPORTING SCIENTER

96. Israel's scienter is supported by the small size of Kitov. Kitov had at most ten employees and consultants during the Class Period. As of December 2015, when the KIT-302 clinical trial data was falsified, Israel was one of the Company's only two full time employees.

The CEO of Kitov would have had full awareness of all information concerning its lead drug candidate, KIT-302.

97. Israel's scienter can also be inferred from the fact that, according to several former consultants of Kitov with knowledge of the clinical trial results, Israel was the individual who directed that the KIT-302 trial's blood pressure data be falsified to show efficacy before being provided to the DMC.

98. Israel's scienter can further be inferred from the fact that, as reported in the publication *Calcalist,* the Israeli Securities Authority reached the conclusion that Israel had knowledge of the misstatements in Kitov's filings with Israeli and American securities authorities.

99. Rock's scienter is supported by the small size of Kitov. Kitov had at most ten employees and consultants during the class period.

100. Rock also had motive to commit fraud because he obtained warrants to purchase additional shares of Kitov stock when Kitov satisfied the DMC that it had met the primary endpoint of the KIT-302 trial.

101. Kitov's scienter can be inferred from the scienter of its officers, Rock and Israel.

PLAINTIFFS' CLASS ACTION ALLEGATIONS

102. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all persons other than defendants who acquired Kitov ADSs during the Class Period and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of Kitov, members of the Individual Defendants' immediate families and their legal representatives, heirs, successors or assigns and any entity in which Officer or Director Defendants have or had a controlling interest.

103. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Kitov securities were actively traded on NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds, if not thousands of members in the proposed Class.

104. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

105. Plaintiffs will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

106. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the Exchange Act were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the financial condition and business Kitov;
- whether Defendants' public statements to the investing public during the Class Period omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;
- whether the Defendants caused Kitov to issue false and misleading SEC filings during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and SEC filing

- whether the prices of Kitov's securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

107. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

108. Plaintiffs will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Kitov ADSs met the requirements for listing, and were listed and actively traded on NASDAQ, a highly efficient and automated market, with over 100,000 shares traded on average weekly during the class period

- As a public issuer, Kitov filed periodic public reports with the SEC and NASDAQ;

- Kitov regularly communicated with public investors via established market communication mechanisms, including through the regular dissemination of press releases via major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services

- Kitov was followed by at least four securities analysts who wrote reports that were widely distributed and publicly available; and

- Unexpected material news about Kitov was rapidly reflected and incorporated into the Company's stock price during the Class Period.

109. Based on the foregoing, the market for Kitov securities promptly digested current information regarding Kitov from all publicly available sources and reflected such information in

the prices of the shares, and Plaintiffs and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

110. Alternatively, Plaintiffs and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information as detailed above.

COUNT I

For Violations of Section 10(b) And Rule 10b-5 Promulgated Thereunder Against All Defendants

111. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

112. This Count is asserted against Defendants is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

113. During the Class Period, Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

114. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

- employed devices, schemes and artifices to defraud;
- made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

- engaged in acts, practices and a course of business that operated as a fraud or deceit upon plaintiffs and others similarly situated in connection with their purchases of Kitov securities during the Class Period.

115. Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of Kitov were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated, or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the securities laws. These defendants by virtue of their receipt of information reflecting the true facts of Kitov, their control over, and/or receipt and/or modification of Kitov's allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning Kitov, participated in the fraudulent scheme alleged herein.

116. Individual Defendants, who are the senior officers and/or directors of the Company, had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Plaintiffs and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements made by them or other Kitov personnel to members of the investing public, including Plaintiffs and the Class.

117. As a result of the foregoing, the market price of Kitov securities was artificially inflated during the Class Period. In ignorance of the falsity of Defendants' statements, Plaintiffs and the other members of the Class relied on the statements described above and/or the integrity of the market price of Kitov securities during the Class Period in purchasing Kitov securities at prices that were artificially inflated as a result of Defendants' false and misleading statements.

118. Had Plaintiffs and the other members of the Class been aware that the market price of Kitov securities had been artificially and falsely inflated by Defendants' misleading statements and by the material adverse information which Defendants did not disclose, they would not have purchased Kitov securities at the artificially inflated prices that they did, or at all.

119. As a result of the wrongful conduct alleged herein, Plaintiffs and other members of the Class have suffered damages in an amount to be established at trial.

120. By reason of the foregoing, Defendants have violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the Plaintiffs and the other members of the Class for substantial damages which they suffered in connection with their purchase of Kitov securities during the Class Period.

121. This action was brought less than five years after the fraud alleged herein occurred, and within two years of when Plaintiffs discovered or should have discovered the fraud with reasonable due diligence.

COUNT II

Violations of Section 20(a) of the Exchange Act
Against the Individual Defendants

122. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

123. During the Class Period, the Individual Defendants participated in the operation and management of Kitov, and conducted and participated, directly and indirectly, in the conduct of Kitov's business affairs. Because of their senior positions, they knew the adverse non-public information about Kitov's misstatement of revenue and profit and false financial statements.

124. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Kitov's

financial condition and results of operations, and to correct promptly any public statements issued by Kitov which had become materially false or misleading.

125. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Kitov disseminated in the marketplace during the Class Period concerning Kitov's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Kitov to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Kitov within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Kitov securities.

126. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Kitov.

127. This action was brought less than five years after the fraud alleged herein occurred, and within two years of when Plaintiffs discovered or should have discovered the fraud with reasonable due diligence.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of himself and the Class, pray for judgment and relief as follows:

(a) declaring this action to be a proper class action, and certifying Plaintiffs as class representatives under Rule 23 of the Federal Rules of Civil Procedure and designating Plaintiffs' counsel as Class Counsel;

(b) awarding damages in favor of Plaintiffs and the other Class members against all Defendants, jointly and severally, together with interest thereon;

(c) awarding Plaintiffs and the Class reasonable costs and expenses incurred in this action, including expert fees; and

(d) awarding Plaintiffs and other members of the Class such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury.

Dated: June 19, 2017

Respectfully Submitted,

POMERANTZ LLP

/s/Jeremy A. Lieberman
Jeremy A. Lieberman
Tamar A. Weinrib
600 Third Avenue, 20th Floor
New York, NY 10016
T: (212) 661-1100
F: (917) 463-1044
jalieberman@pomlaw.com
taweinrib@pomlaw.com

Lead Counsel for Plaintiffs